



JFW

141-424

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT OPERATION

In re Application of:

Kositprapa et al.

Serial No.: **10/664,803**

Group Art Unit: --

Filed: **September 19, 2003**

Examiner: --

For: **NOVEL PHARMACEUTICAL FORMULATION CONTAINING A BIGUANIDE
AND A THIAZOLIDINEDIONE DERIVATIVE**

New York, NY 10036
December 22, 2003

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

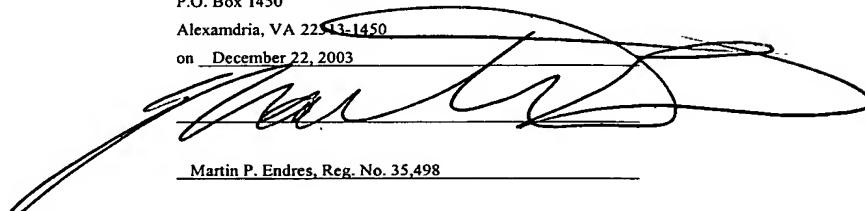
INFORMATION DISCLOSURE STATEMENT

Sir:

The following statement of relevance is submitted with the accompanying
Form PTO/SB/08A.

<u>Document Designation</u>	<u>Relevance</u>
AA U.S.P. 3,174,901	Relates to a process for the oral treatment of diabetes.
AB U.S.P. 3,960,949	Relates to 1,2-biguanides.
AC U.S.P. 4,166,800	Relates to a process for preparation of microspheres.

I hereby certify that this correspondence is being deposited with the
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on December 22, 2003


Martin P. Endres, Reg. No. 35,498

<u>Document Designation</u>	<u>Relevance</u>
AD U.S.P. 4,389,330	Relates to a microencapsulation process.
AE U.S.P. 4,687,777	Relates to a thiazolidinedione derivative, useful as an antidiabetic agent.
AF U.S.P. 4,839,177	Relates to a system for the controlled-rate release of active substances.
AG U.S.P. 4,891,223	Relates to a controlled release delivery coating formulation for bioactive substances.
AH U.S.P. 4,968,507	Relates to a controlled porosity osmotic pump.
AI U.S.P. 5,294,770	Relates to a laser tablet treatment system.
AJ U.S.P. 5,356,913	Relates to the use of insulin sensitizing agents to treat hypertension.
AK U.S.P. 5,376,771	Relates to a high speed process for preparing orifices in pharmaceutical dosage forms.
AL U.S.P. 5,478,852	Relates to a use of thiazolidinedione derivatives and related antihyperglycemic agents in the treatment of impaired glucose tolerance in order to prevent or delay the onset of noninsulin-dependent diabetes mellitus.
AM U.S.P. 5,602,133	Relates to a use of thiazolidinedione derivatives and related antihyperglycemic agents in the treatment of disease states at risk for progressing to noninsulin-dependent diabetes mellitus.
AN U.S.P. 5,658,474	Relates to a method and apparatus for forming dispenser delivery ports.
AO U.S.P. 5,681,584	Relates to a controlled release drug delivery device.
AP U.S.P. 5,698,220	Relates to an asymmetric membrane for use in drug delivery devices.
AQ U.S.P. 5,719,188	Relates to the use of insulin sensitizing agents to treat hypertension.
AR U.S.P. 5,859,037	Relates to sulfonylurea-glitazone combinations for diabetes.

AS U.S.P. 5,916,584	Relates to a controlled release container with a core and an outer shell.
AT U.S.P. 5,952,356	Relates to a pharmaceutical composition.
AU U.S.P. 5,955,106	Relates to a pharmaceutical preparation containing metformin and a process for producing it.
AV U.S.P. 6,011,049	Relates to drug combinations for treating diabetes.
AW U.S.P. 6,031,004	Relates to salts of metformin.
AX U.S.P. 6,099,859	Relates to a controlled release oral tablet having a unitary core.
AY U.S.P. 6,153,632	Relates to a method and composition for the treatment of diabetes.
AZ U.S.P. 6,191,162	Relates to a method of reducing serum glucose levels.
BA U.S.P. 6,248,363	Relates to a solid carrier for improved delivery of active ingredients in pharmaceutical compositions.
BB U.S.P. 6,291,495	Relates to a method and composition for the treatment of diabetes.
BC U.S.P. 6,296,874	Relates to a core formulation comprising troglitazone and a biguanide.
BD U.S.P. 6,329,403	Relates to a pharmaceutical composition for the treatment of diabetes.
BE U.S.P. 6,383,471	Relates to a composition and method for improved delivery of ionizable hydrophobic therapeutic agents.
BF U.S.P. 6,403,121	Relates to a core formulation.
BG US 2002/0071866	Relates to a dosage form having a barrier layer to laser ablation.
BH U.S.P. 6,451,342	Relates to a core formulation comprised of troglitazone and a biguanide.

BI U.S.P. 6,475,521	Relates to a biphasic controlled release delivery system for high solubility pharmaceuticals.
BJ U.S.P. 6,524,621	Relates to a core formulation.
BK US 2003/0113371	Relates to a composition and method for maintaining blood glucose level by employing a hydrophilic matrix based oral controlled release antidiabetic composition.
BL US 2003/0118647	Relates to an extended release tablet of metformin.
BM US 2003/0118649	Relates to a drug delivery device.
BN U.S.P. 6,599,284	Relates to an osmotic device having a preformed passageway that increases in size.
CA WO 96/09823	Relates to a hypoglycemic agent from cryptolepis.
CB WO 98/11879	Relates to a gastric-retentive, oral drug dosage form for the controlled-release of sparingly soluble drugs and insoluble matter.
CC WO 98/55107	Relates to a gastric-retentive oral drug dosage form for controlled release of highly soluble drugs.
CD WO 99/47128	Relates to a biphasic controlled release delivery system for high solubility pharmaceuticals.
CE WO 99/55320	Relates to an oral formulation comprising a biguanide and an organic acid.
CF WO 00/28989	Relates to a pharmaceutical composition for modified release of an insulin sensitizer and another antidiabetic agent.
CG WO 00/72827	Relates to porous drug matrices and methods of manufacture thereof.
CH WO 01/35940	Relates to a composition comprising a thiazolidinedione metformin hydrochloride.
CI WO 01/35941	Relates to a composition comprising a thiazolidinedione metformin hydrochloride.
CJ WO 01/82875	Relates to a core formulation comprising pioglitazone and a biguanide.

CK	Relates to a sustained release pharmaceutical composition containing metformin and a method for its production.
WO 02/28181	
CL	Relates to a pharmaceutical composition.
WO 03/004009	
CM	Relates to a formulation of an erodible, gastric retentive oral dosage form using in vitro disintegration test data.
WO 03/35029	
CN	Relates to an extended release pharmaceutical tablet of metformin.
WO 03/047529	
CO	Relates to a controlled porosity osmotic pump.
EP 0 169 105	
CP	Relates to metformin dosage formulation.
EP 0 283 369	
CQ	Relates to a system for the controlled release of active agents and a process for its preparation.
EP 0 381 181	
CR	Relates to a pharmaceutical composition for use in treatment of diabetes.
EP 0 749 751	
CS	Relates to a synergistic combination comprising an insulin sensitizer and a HMG-CoA reductase inhibitor for treating arteriosclerosis.
EP 0 753 298	
CT	Relates to a pharmaceutical preparation containing metformin and a process for producing it.
EP 0 781 129	
DA	Relates to a sustained release metformin dosage form.
P. Karttunen et al. International Journal of Clinical Pharmacology, Therapy and Toxicology, “The pharmacokinetics of metformin: a comparison of the properties of a rapid-release and a sustained-release preparation” Vol. 21 No. 1 – 1983, pp. 31-36.	
DB	Relates to a sustained release metformin dosage form.
P.J. Pentikainen International Journal of Clinical Pharmacology, Therapy and Toxicology, “Bioavailability of metformin. Comparison of solution, rapidly dissolving tablet, and three sustained release products” Vol. 24 No. 4 – 1986, pp. 213-220	

DC Relates to a sustained release metformin dosage form.
Finnish Monograph of the Diformin®
Retard table
with English translation

DD Relates to metformin dosage form.
O.J. Lucis, MD, Ph. D., MSC
Canada Medical Association J.
Pharmacologic Update
“The status of metformin
in Canada” Vol. 128
January 1, 1983 pgs. 24-26

DE Relates to pioglitazone.
G. Belcher and D.R. Matthews
Experiment and Clinical
Endocrinology & Diabetes
“Safety and tolerability
of pioglitazone” Suppl 2
(2000) pgs. 267-273

DF Relates to a pioglitazone and metformin dosage forms.
Daniel Einhorn, MD et al.
Clinical Therapeutics
“Pioglitazone Hydrochloride in
Combination with Metformin in
the Treatment of Type 2 Diabetes
Mellitus: A Randomized, Placebo-
Controlled Study”,
Vol. 22 No. 12, 2000 pgs. 1395-1413

DG Relate to pioglitazone.
National Institute for Clinical Excellence
Technology Appraisal Guidance – No. 21
“Guidance on the Use of Pioglitazone for
Type 2 Diabetes Mellitus”
March 2001, pgs. 1-13

DH Relates to pioglitazone.
The Pharmaceutical Journal
Vol. 265, No. 7122, p. 710
November 11, 2000 Clinical
(abstract only)

DI Relates to a metformin extended-release tablet.
Product Labeling for
Glucophage® XR (July 2002)

DJ
ADA Professional Section
Member Supplement
047 and 0503-506 (Poster)
p. A110; A117

Relates to combination therapy with pioglitazone and insulin in patients with Type 2 diabetes.

DK Relates to an insulin-sensitizing diabetes agent.
Website www.findarticles.com
Clinician Reviews
“Insulin-Sensitizing Diabetes Agent”
September 1999

DL Relates to pioglitazone dosage formulation.
ACTOS® product label
Physician's Desk Reference
55TH Edition, pp. 3171-3175

DM Relates to Medabet which is a tablet containing metformin.
Rote Liste No. 11081 the Medicament
Medabet of MEDICE, Chem.-
Pharm. Fabrik Pütter GmbH & Co.
KG, Kuhloweg 37-39 Iserlohn/Germany,
Editio Cantor Verlag für Medizin und
Naturwissenschaften GmbH, 1993.

Full text copies of the prior art are enclosed herewith. It is respectfully requested that this art be considered by the Examiner in the above-entitled application and made of record therein.

Pursuant to 37 C.F.R. §1.97 it is believed that no fee is required for consideration of this Information Disclosure Statement. If a fee is required, the Commissioner is hereby authorized to charge Deposit Account No. 08-1540.

~~Respectfully submitted,~~

Martin P. Endres
Reg. No. 35,498

MAILING ADDRESS:

HEDMAN & COSTIGAN, P.C.
1185 Avenue of the Americas
New York, NY 10036
(212) 302-8989



DEC 29 2003

PTO/SB/08A (10-01)

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Substitute for form 1449A/PTO		<i>Compl t if Known</i>
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Application Number 10/664,803
(use as many sheets as necessary)		Filing Date September 19, 2003
		First Named Inventor Unchalee Kositprapa
		Art Unit
		Examiner Name
Sheet 1	of 5	Attorney Docket Number 141-424

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 5

Complaint if Known

Application Number	10/664,803
Filing Date	September 19, 2003
First Named Inventor	Unchalee Kositprapa
Art Unit	
Examiner Name	
Attorney Docket Number	141-424

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (If known)			
	AA	us-3,174,901	03-23-1965	Sterne	
	AB	us-3,960,949	06-01-1976	Ahrens et al.	
	AC	us-4,166,800	09-04-1979	Fong	
	AD	us-4,389,330	06-21-1983	Tice et al.	
	AE	us-4,687,777	08-18-1987	Meguro et al.	
	AF	us- 4,839,177	06-13-1989	Colombo et al.	
	AG	us- 4,891,223	01-02-1990	Ambegaonkar et al.	
	AH	us- 4,968,507	11-06-1990	Zentner et al.	
	AI	us- 5,294,770	03-15-1994	Riddle et al.	
	AJ	us- 5,356,913	10-18-1994	Colca	
	AK	us- 5,376,771	12-27-1994	Roy	
	AL	us- 5,478,852	12-26-1995	Olefsky et al.	
	AM	us- 5,602,133	02-11-1997	Antonucci et al.	
	AN	us- 5,658,474	08-19-1997	Geerke	
	AO	us-5,681,584	10-28-1997	Savastano et al.	
	AP	us- 5,698,220	12-16-1997	Cardinal et al.	
	AQ	us-5,719,188	02-17-1998	Colca	
	AR	us- 5,859,037	01-12-1999	Whitcomb	
	AS	us- 5,916,584	06-29-1999	O'Donoghue et al.	
	AT	us- 5,952,356	09-14-1999	Ikeda et al.	

FOREIGN PATENT DOCUMENTS

Examiner Signature	Date Considered	
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***EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2

of 5

C mplet if Known

Application Number	10/664,803
Filing Date	September 19, 2003
First Named Inventor	Unchalee Kositprapa
Art Unit	
Examiner Name	

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AU	us- 5,955,106	09-21-1999	Moeckel et al.		
AV	us-6,011,049	01-04-2000	Whitcomb		
AW	us-6,031,004	02-29-2000	Timmins et al.		
AX	us-6,099,859	08-08-2000	Cheng et al.		
AY	us-6,153,632	11-28-2000	Rieveley		
AZ	us- 6,191,162	02-20-2001	Byrd et al.		
BA	us- 6,248,363	06-19-2001	Patel et al.		
BB	us- 6,291,495	09-18-2001	Rieveley		
BC	us- 6,296,874	10-02-2001	Cutie et al.		
BD	us- 6,329,403	12-11-2001	Odaka et al.		
BE	us- 6,383,471	05-07-2002	Chen et al.		
BF	us- 6,403,121	06-11-2002	Adjei et al.		
BG	us- 2002/0071866	06-13-2002	Geerke		
BH	us- 6,451,342	09-17-2002	Adjei et al.		
BI	us-6,475,521	11-05-2002	Timmins et al.		
BJ	us- 6,524,621	02-25-2003	Adjei et al.		
BK	us-2003/0113371	06-19-2003	Dhawan et al.		
BL	us- 2003/0118647	06-26-2003	Seth		
BM	us- 2003/0118649	06-26-2003	Gao et al.		
BN	us- 6,599,284	07-29-2003	Faour		

FOREIGN PATENT DOCUMENTS

Examiner Initials ¹	Cite No. ¹	Foreign Patent Document Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
CA	WO 96/09823	04-04-1996	Luo et al.			
CB	WO 98/11879	03-26-1998	Shell et al.			
CC	WO 98/55107	12-10-1998	Shell et al.			
CD	WO 99/47128	09-23-1999	Timmins et al.			
CE	WO 99/55320	11-04-1999	Nishii et al.			
CF	WO 00/28989	05-25-2000	Lewis et al.			
CG	WO 00/72827	12-07-2000	Straub et al.			
CH	WO 01/35940	05-25-2001	Lewis et al.			
CI	WO 01/35941	05-25-2001	Lilliot et al.			
CJ	WO 01/82875	11-08-2001	Cutie et al.			

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SignatureDate
Considered

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Substitute for form 1449A/PTO		<i>Complete if Known</i>	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Application Number	10/664,803
		Filing Date	September 19, 2003
		First Named Inventor	Unchalee Kositprapa
		Art Unit	
		Examiner Name	
Sheet	3	of	5
		Attorney Docket Number	

U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

Examiner Initials ^a	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
CK	WO 02/28181		04-11-2002	Gidwani et al.		
CL	WO 03/004009		01-16-2003	Matharu et al.		
CM	WO 03/035029		05-01-2003	Louie-Helm et al.		
CN	WO 03/047529		06-12-2003	Seth et al.		
CO	EP 0 169 105		01-22-1986	Zentner et al.		
CP	EP 0 283 369		09-21-1988	Wiernsperger et al.		
CQ	EP 0 381 181		08-08-1995	Wenzel et al.		
CR	EP 0 749 751		12-27-1996	Ikeda et al.		
CS	EP 0 753 298		11-21-2001	Tsujita et al.		
CT	EP 0 781 129		07-02-2003	Moeckel et al.		

Examiner Signature		Date Considered	
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¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 4 of 5

Compl t if Known

Application Number	10/664,803
Filing Date	September 19, 2003
First Named Inventor	Unchalee Kositprapa
Group Art Unit	
Examiner Name	

Attorney Docket Number 141-424

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher city and/or country where published	T ²
	DA	P. Karttunen et al., International Journal of Clinical Pharmacology, Therapy and Toxicology, "The pharmacokinetics of metformin: a comparison of the properties of a rapid release and a sustained-release preparation" Vol. 21, No. 1 - 1983, pp. 31-36.	
	DB	P.J. Pentikainen, International Journal of Clinical Pharmacology, Therapy and Toxicology, "Bioavailability of metformin. Comparison of solution, rapidly dissolving-tablet, and three-sustained-release-products", Vol. 24, No. 4 - 1986, pp. 213-220.	
	DC	Finnish Monograph of the Diformin®, Retard tablet, with English translation	
	DD	O.J. Lucis, MD, Ph.D., MSC, Canada Medical Association J. Pharmacologic Update "The status of metformin in Canada" Vol. 128, January 1, 1983, pgs. 24-26.	
	DE	G. Belcher and D.R. Matthews Experiment and Clinical Endocrinology & Diabetes, "Safety and tolerability of pioglitazone" Suppl. 2 (2000) pgs. 267-273.	
	DF	Daniel Einhorn, MD et al., Clinical Therapeutics "Pioglitazone Hydrochloride in Combination with Metformin in the Treatment of Type 2 Diabetes Mellitus: A Randomized, Placebo-Controlled Study", Vol. 22, No. 12, 2000 pgs. 1395-1413.	
	DG	National Institute for Clinical Excellence Technology Appraisal Guidance - No. 21, "Guidance on the Use of Pioglitazone for Type 2 Diabetes Mellitus" March 2001, pgs. 1-13.	
	DH	The Pharmaceutical Journal, Vol. 265, No. 7122, p. 710 November 11, 2000 Clinical (abstract only).	

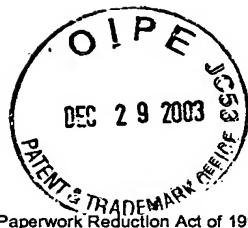
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Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 5 of 5

Complaint if Known	
Application Number	10/664,803
Filing Date	September 19, 2003
First Named Inventor	Unchalee Kositprapa
Group Art Unit	
Examiner Name	
Attorney Docket Number	141-424

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Signature		Date Considered
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